Reexamination Control Number **90/006,090**
Application Number **10/626,486**
Response dated **28 June 2005**
Reply to Office Action of **29 April 2005**

Remarks

This paper is being filed in response to the Office Action mailed on 29 April 2005 in Reexamination Proceeding 90/006,090. A copy of this paper is also being filed in Reissue Application 10/626,486. These two proceedings were merged pursuant to the Decision mailed on 23 May 2005.

In this response, Applicant has not amended the claims, has not added any new claims, and has not cancelled any claims. Therefore, Claims 1–23 remain pending in this application. Claims 1 and 14 are independent. Claims 14, 15 and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sher, *Surgery for Hyperopia & Presbyopia*, October 1997, Williams & Wilkens, First Edition, pages 33–36 ("Sher"). Claims 1–13, 16–21 and 23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sher in view of U.S. Patent 5,520,679 ("Lin").

Claim Rejections Under 35 U.S.C. § 103(a) based on Sher.

Claims 14, 15 and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sher. Claim 14 is independent, and Claims 15 and 22 depend from Claim 14.

Sher discloses a procedure to reverse presbyopia that involves cutting multiple "mini-radial" incisions over the ciliary body in the anterior sclera. According to Sher, the incisions allow the sclera to expand, thereby resulting in an increased scleral diameter over the ciliary body. Sher teaches that the increased scleral diameter provides increased area for ciliary muscle action and consequent increased zonular effectiveness in changing the focal power of the patient's lens. In the technique disclosed in Sher, a steel or diamond blade is used to create the incisions. The desired incision depth is between 65% and 70% of the scleral depth. Sher discloses that making the incisions too deep may cause infection and hemorrhage. See Sher, pages 34 and 35.

In contrast to the technique disclosed in Sher, independent Claim 14 recites, among other things, "cutting at least three spaced apart, substantially radial lines in the

scleral tissue of a patient's eye outside the limbus to a depth of 80–90% of the thickness of the scleral tissue'. Acknowledging that Sher fails to disclose the 80% to 90% element, the Examiner has taken the position that cutting to this depth "would have been within the level of skill of the artisan to select to optimize the procedure". Applicant respectfully traverses the Examiner's position.

At the outset, the Examiner fails to give sufficient weight to Sher's teaching that cutting to greater than 65% to 70% of the scleral depth may cause infection and hemorrhage. A *prima facie* case of obviousness may be rebutted by showing that the art, *in any material respect*, teaches away from the claimed invention. See MPEP 2144.05, paragraph III. Sher clearly teaches away from cutting to a depth of 80% to 90% of the scleral thickness, since Sher teaches that cutting to a depth greater than 65% to 70% may cause infection and hemorrhage.

Furthermore, proceeding contrary to accepted wisdom in the art is evidence that a claimed invention is not obvious. See MPEP 2145, paragraph X.D.3. Again, Sher teaches that the accepted wisdom of the prior art is that cutting to greater than 65% to 70% of the scleral depth can disadvantageously cause infection and hemorrhage. By cutting to a greater depth of 80% to 90% of the scleral thickness, Applicant is proceeding directly contrary to the conventional wisdom in the art.

Additionally, a particular parameter must first be recognized as a "result-effective variable" before the determination of the optimum range of said variable might be characterized as routine experimentation. See MPEP 2144.05, paragraph II.D. Sher certainly does not recognize that the incision depth is a result-effective variable. Indeed, Sher contains little discussion of incision depth beyond the one sentence stating that the desired incision depth is between 65% and 70% of the scleral thickness. In actuality, Sher teaches that the *number of incisions* is the result-effective variable of the disclosed technique, noting that "more incisions produce more effect" (see page 34, column 2) and "for greater effect the procedure can be titrated by adding up to eight more incisions any time after placement of the original eight" (see page 35, column 1).

Based on the foregoing, Applicant respectfully submits that Claim 14 is not obvious in view of the teachings of Sher, and requests that this rejection be withdrawn.

Furthermore, because Claims 15 and 22 depend from independent Claim 14, Applicant respectfully submits that these claims are allowable for at least the same reasons that Claim 14 is allowable.

Claim Rejections Under 35 U.S.C. § 103(a) based on Sher and Lin.

Claims 1–13, 16–21 and 23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sher in view of U.S. Patent 5,520,679 ("Lin"). Claim 1 is independent, and Claims 2–13 depend from Claim 1. Claims 16–21 and 23 depend from independent Claim 14.

Lin discloses techniques for performing laser surgery on the cornea to reshape the corneal surface to treat certain listed vision disorders, *none of which include presbyopia*. In the techniques disclosed in Lin, laser ablation is used to directly alter the shape of the corneal surface to provide a *refractive* vision correction. That is, in Lin, the surgically repaired surface is the corneal surface through which light passes. Consequently, the particular laser parameters that Lin teaches are specifically related to altering the shape of the corneal surface to change the way light passes through the reshaped cornea.

In contrast to the teachings of Lin, independent Claim 1 recites a laser beam ophthalmological surgery method for treating presbyopia in a patient's eye by, among other things, photo-ablating *scleral tissue outside the limbus*. Lin clearly does not mention ablation of scleral tissue outside the limbus to correct presbyopia (and in fact fails to mention treatment of presbyopia entirely). Yet, the Examiner has used the teachings of Lin to modify the teachings of Sher. Furthermore, as discussed above, Sher discloses methods of presbyopia treatment using a blade to cut incisions in the scleral tissue.

1. It would not be obvious to modify Sher based on Lin's teachings.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation to modify or combine references. See MPEP 2143. Applicant respectfully traverses the Examiner's suggestion that it would be obvious to modify the methods

disclosed in Sher to use a laser instead of a blade to make the scleral incisions. The Examiner has taken the position that this modification would be motivated by the fact that "a laser would permit greater precision and flexibility in the carrying out the cutting procedure". Neither Sher nor Lin provides this motivation to modify Sher.

The techniques disclosed in Lin operate under a completely different principle of operation than those disclosed in Sher, and therefore the teachings of Lin cannot be used to modify the teachings of Sher. See MPEP 2143.01. Specifically, Lin discloses methods for reshaping the scleral surface using a refractive technique, while Sher discloses methods for providing increased area for ciliary muscle action and thus increased zonular effectiveness. The technique disclosed in Lin is used to modify the optical properties of the laser-ablated portion of the eye, while the technique disclosed in Sher is used to produce a change in the dimensions of the eye via scleral expansion. In the technique disclosed in Sher, the size of the globe of the eye changes in certain regions, but *the shape of the cornea is entirely unaltered* (see Sher, page 34, column 2).

Because it is limited to corneal reshaping techniques, Lin contains no disclosure of appropriate techniques for cutting the sclera outside the limbus to provide increased area for ciliary muscle action. Notably, the vision disorders that Lin discloses as being treatable using the techniques disclosed in Lin do not even include presbyopia. Furthermore, as discussed above in connection with Claim 14, nether Sher nor Lin contain any suggestion of cutting to 80% to 90% of the depth of the scleral tissue. Indeed, Sher teaches away from cutting to greater than 65% to 70% of the depth of the scleral tissue because of potential complications. Therefore, an artisan seeking to improve the methods disclosed in Sher for treating presbyopia would have no reason to look to the disclosure of Lin for potential improvements or modifications.

In summary, the teachings of Sher and Lin are unrelated. The ablation is performed on different portions of the eye in Sher (the sclera) as compared to Lin (the cornea). Sher teaches ablation to change the overall size of the non-transparent portions of the eye, while Lin teaches corneal reshaping to directly alter the geometry of the transparent portion of the eye through which light passes. Neither of the references illustrates or suggests a reason to take the teachings related to corneal reshaping and

apply them to the non-transparent scleral tissue. Therefore, because these techniques do not address the same problem, and do not address it in the same way, there can be no motivation to combine these references within the context of a rejection under 35 U.S.C. § 103.

2. All of the claim limitations are not taught by the combination of Sher and Lin.

To establish a *prima facie* case of obviousness, the prior art references must teach or suggest all of the claim limitations. See MPEP 2143. Applicant respectfully traverses the Examiner's suggestion that the combination of Shear and Lin suggests all of the elements of Claims 1–13, 16–21 and 23. Claims 1–13 recite, among other things, controlling a scanning mechanism to photo-ablate the scleral tissue outside the limbus to a depth of 80% to 90% of the thickness of the scleral tissue. Likewise, by virtue of their dependence on independent Claim 14, Claims 16–21 and 23 recite, among other things, cutting at least three spaced apart, substantially radial lines in the scleral tissue of a patient's eye outside the limbus to a depth of 80% to 90% of the thickness of the scleral tissue.

Neither Lin nor Sher teach these elements, and it would not be obvious to modify Sher to perform the method by cutting to the increased depth of 80% to 90% of the thickness of the scleral tissue, as discussed above with respect to Claim 14. In fact, Lin includes no disclosure of methods of treating presbyopia. Moreover, Sher actually teaches away from cutting to a depth of 80% to 90% of the scleral thickness.

Conclusion.

Based on the foregoing, Applicant respectfully submits that Claim 1 is not obvious in view of the combined teachings of Sher and Lin, and requests that this rejection be withdrawn. Furthermore, because Claims 2–13 depend from independent Claim 1, Applicant respectfully submits that these claims are allowable for at least the same reasons that Claim 1 is allowable. Likewise, Applicant respectfully submits that Claims 16–21 and 23 are not obvious in view of the combined teachings to Sher and Lin, and requests that these rejections also be withdrawn. Finally, as mentioned above,

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Applicant respectfully submits that it would not be obvious to modify the teachings of Sher to make incisions in the scleral tissue outside the limbus to a depth of 80% to 90% of the thickness of the scleral tissue.

In view of the foregoing comments, Applicant respectfully requests that the Examiner pass the pending claims to allowance.

Respectfully submitted,

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